UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,181	09/24/2003	Caroline Osterhoff	35-268	5220

7590 05/16/2006

Millen, White, Zelano & Branigan, P.C.
2200 Clarendon Boulevard
Suite 1400
Arlington, VA 22201

EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/668,181	OSTERHOFF ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,17 and 19-33* is/are pending in the application.

4a) Of the above claim(s) *6-14,19,20 and 23-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 17 21 22 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 1 to 14, 17 and 19 to 33 are pending in the instant application. Claims 15, 16 and 18 have been canceled and claims 31 to 33 have been added as requested by Applicant in the correspondence filed 28 February of 2006.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 6 to 14, 19, 20 and 23 to 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the correspondence filed 05 October of 2005.

5) Claims 1 to 5, 17, 21, 22 and 31 to 33 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record as applied to claims 1 to 5, 17, 21 and 22 in section 3 of the previous office action. As stated therein, the instant claims are drawn to an isolated mammalian epididymis-specific receptor that lacks a specific and substantial utility in currently available form because the instant application does not disclose an established specific biological role for this protein or its significance to a particular disease, disorder of physiological process which one would wish to manipulate for a desired clinical effect.

Applicant has traversed this rejection on the basis that "[t]he specification describes numerous credible, specific, and substantial utilities for the claimed

polypeptides, including the use of antibodies for immunological detection of epididymis tissue (e.g., Page 12, line 20-Page 13, line 5) and the use of antibodies (and other ligands) for contraception purposes (e.g., Page 14, line 28-Page 15, line 10).

Applicant was provided with a detailed explanation of why the employment of a protein of the instant invention as a tissue marker did not constitute a specific and substantial utility for that protein in the original rejection. As essentially stated therein, the employment of a protein of the instant invention, or a nucleic acid encoding that protein, as a tissue specific marker is not a substantial or specific utility. All human proteins can invariably be classified into two categories, those which are expressed in a tissue or developmentally specific manner and those which are expressed ubiquitously. It can be alleged that any protein that is expressed in a tissue specific manner can be employed to detect the tissue in which it is expressed in a sample. Alternately, a human protein that is expressed ubiquitously can be employed to detect the presence of any human tissue in a sample. Such utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility.

One could just as readily argue that any purified compound having a known structure could be employed as an analytical standard in such processes as nuclear magnetic resonance (NMR), infrared spectroscopy (IR), and mass spectroscopy as well as in polyacrylamide gel electrophoresis (PAGE), high performance liquid chromatography (HPLC) and gas chromatography. None of these processes could be practiced without either calibration standards having known molecular structures or, at least, a range of molecular weight markers having known molecular weights. One could further extrapolate upon this premise by asserting that any item having a fixed measurable parameter can be employed to calibrate any machine or process which measures that parameter. For example, any item having a constant mass within an acceptable range can be employed to calibrate a produce scale in a grocery store. The calibration of produce scales is certainly an important function since most states require produce scales to be calibrated and certified. Therefore, to accept Applicant's arguments that the protein of the instant invention is useful as a marker because its expression is limited to a particular tissue or organ would be comparable to conceding that any object of fixed mass has *prima facie* utility as a weight standard, irrespective of any other properties possessed by that object. It was just such applications that the court appeared to be referring to when it expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)). Because the steroid compound which was the subject of that decision had a known structure and molecular weight it could have readily been employed as a molecular standard at that

time. Further, because that compound was a hydrocarbon it certainly could have been employed in the well known process of combustion for purposes of lighting and/ or the generation of heat. The generation of heat by combustion of hydrocarbons certainly was and remains an important process. Irrespective of such obvious utilities, the court still held that the compound produced by the process at issue in *Brenner v. Manson* did not have a specific and substantial utility.

To grant Applicant a patent encompassing an isolated polypeptide corresponding to all or a portion of a naturally occurring human protein of as yet undetermined biological significance would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" *(Brenner v. Manson, Ibid)*. To grant Applicant a patent on the claimed protein based solely upon an assertion that it can be employed as a tissue marker is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted and would be no different than granting a patent on the process disputed in *Brenner v. Manson* on the premise that the steroid produced thereby was useful as an analytical standard or as a combustible fuel source.

In so far as Applicant urges that a receptor protein of the instant invention can be employed to identify antibodies or other ligands thereto for contraceptive purposes, Applicant has apparently chosen to ignore the teachings of the Gottwald et al. publication provided with Applicant's last response. This publication, in describing the

possibility of employing a protein of the instant invention identified therein as "HE6" in the identification of male contraceptives, concludes by stating that "the screening of orphan receptors such as HE6 directly for antagonists is often not feasible", "[I]n many cases, ligand identification is a first mandatory step in the screening process" and that "[b]eside HE6, several other male-specific key factors are already described, increasing the possibility that a drug for non-hormonal male contraception could be developed in the near future". This publication is dated 2006, fully eight years after applicant's earliest priority application upon which the instant application is based, and yet the art clearly does not consider the claimed protein to be a viable target for the identification of male contraceptives in its presently available form. It is a matter of law that an invention must have a specific and substantial utility "in currently available form", which precludes the need for further research, if that research is needed to establish a utility for the claimed invention (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)). Before one could even consider the use of a protein of the instant invention as a potential target for a male contraceptive, one would first have to discover the physiological consequences of agonizing and antagonizing that protein and if, in fact, that protein is actually capable of modulating a desired effect relative to fertility. In order to determine the reproductive consequences of agonizing or antagonizing that protein, one must first identify an agonist or antagonist thereto as described in the Gottwald et al. publication as "a first mandatory step in the screening process". Clearly, substantial additional experimentation is required to identify or reasonably confirm the use of the claimed

protein in the identification of male contraceptives and, therefore, the claimed invention lacks a specific and substantial utility in currently available form.

In so far as Applicant relies upon a previously provided Declaration under 37 C.F.R. § 1.132, Applicant is advised that there are no such declarations of record in the instant application.

Applicant's reliance on *In re Brana*, 51 F.3d 1560,1566, 34 USPQ2d 1436 ,1441 (Fed. Cir. 1995) is misplaced. That court decision determined that a compound which belonged to a family of compounds known to have anti-tumor activity, which is a common and well established specific and substantial utility for that family of compounds, would be reasonably expected to have anti-tumor activity in light of positive *in vitro* data with respect to that particular compound since that data has proven to be an indicator of anti-cancer activity by other members of that family. The protein of the instant invention does not belong to a family of compounds with a common well established specific and substantial utility. The utility of those members of the receptor family to which the claimed protein in the instant application belongs lies in the knowledge that each of them modulates a specific physiological activity in response to a specific ligand. Since the instant specification does not credibly disclose the identity of a native ligand for the protein of the instant invention, the disclosure of the fact that a protein of the instant invention is a member of the G protein-coupled receptor family is not particularly useful.

Applicant has cited the O'Rand et al. publication (Science 306:1 189, 2004) in support of the assertion that male immunocontraception has been demonstrated to be

effective in a primate animal model, and is therefore an established practical utility. It is noted that this publication was unavailable to an artisan in 1998, Applicant's claimed priority date. As explained above, it is a matter of law that Applicant can not rely upon discoveries made by themselves or others subsequent to the filing of a patent application to complete the claimed invention. Further, O'Rand does not employ a G protein-coupled receptor in the method disclosed therein; they employ a protease inhibitor. The only feature that G protein-coupled receptors and protease inhibitors share is that they are both proteins. One of ordinary skill in the art of reproductive physiology would not reasonably extrapolate from O'Rand et al. to conclude that the administration of any protein expressed in the epididymis will result in an immune reaction leading to male sterility.

6) Claims 1 to 5, 17, 21 and 22 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

7) Claims 1 to 3, 5, 17 and 31 to 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7.1) Claims 1 to 3, 5, 17 and 31 to 33 are vague and indefinite in reference to the term "derivative". As stated in the original rejection, because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "derivative" of a protein having the amino acid sequence presented in SEQ ID NO:2 of the instant application an artisan can not

determine if a compound which meets all of the other limitations of a claim, if any, would then be included or excluded from the claimed subject matter by the presence of this limitation. Applicant has traversed this rejection on the premise that the text beginning in line 30 on page 9 of the instant specification provides the requisite definition. Applicant is advised that it is precisely because the text referred to by Applicant does not identify that property or combination of properties which is unique to and, therefore, definitive of a "derivative" of a protein of the instant invention that this rejection was made.

7.2) Claims 2, 3, 5, 31 and 32 are vague and indefinite because they appear to be drawn to both a protein and a derivative or fragment, each of which appears to be an alternative embodiment of the other. Claim 1 is drawn to the alternate embodiments "a protein", "a derivative" or "a fragment". Claim 2 is drawn to "a protein " and "wherein said derivative or fragment comprises". If it is Applicant's intent that claim 2 be limited to a derivative or fragment, then it should refer to "a derivative or fragment of clam 1" since claim 1 provides antecedent basis for each of these three alternate embodiments.

8) Claims 1 to 5, 17, 21, 22 and 31 to 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Osterhoff et al. publication (DNA and Cell Biol. 16(4):379-389, Apr. 1997). Applicant is advised that, because the previous application did not meet the "how to use" requirement of 35 U.S.C. § 112, first paragraph, with respect to the now claimed invention, it is unavailable to the instant application under 35 U.S.C. § 120.

9) Applicant's arguments filed 28 February of 2006 have been fully considered but they are not persuasive.

10) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11) This application contains claims 6 to 14, 19, 20 and 23 to 30, which are drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
GROUP 1800